Knowledge Acquisition Session Report
NCI – DCP Protocol Information Office

KA Session Date: May 16, 2000 **Time:** 1:00 – 3:00 P.M.

Session Topic: PIO Information Processes and Procedures

Knowledge Analysts: Bill McCurry, Robert Harding – ScenPro, Inc.; Lisa Chatterjee, Oracle.

Organization: Protocol Information Office, NCI Division of Cancer Prevention

Session Location: Rockville, Maryland

Type of Session:

_____ Interview _____ Task Analysis _____ Scenario Analysis
____ Concept Analysis _____ Observation X___ Structured Interview
_____ Other:

Documentation: KA Session Report

General Topic Area

Division of Cancer Prevention – Protocol Information Office: Information Processes and Procedures.

Session Goal

To focus on NCI vendor Clinical Chemoprevention Study Associates' role in the Division of Cancer Prevention's mission.

Report Summary

CCS (Clinical Chemoprevention Study Associates) operates under two contracts with the NCI: a support contract and a monitoring contract. CCS personnel support almost every aspect of DCP's (Division of Cancer Prevention) clinical research efforts. CCS personnel perform many of the clinical trial monitoring tasks for DCP. CCS personnel also perform some activities that are not specifically covered by either contract. CCS and DCP personnel communicate frequently regarding DCP research studies. Many communications between DCP and CCS involve activities from both the monitoring and the support contracts. PIO personnel have relatively little involvement with DCP research studies during Implementation. Implementation is the period between protocol approval and the first patient accrual.

Clinical Chemoprevention Study Associates (CCS)

Clinical Chemoprevention Study Associates (CCS) holds two NCI contracts. One contract covers pre-clinical and post-clinical support of DCP research studies. The other contract covers clinical monitoring of DCP research studies. CCS personnel work closely with Medical Monitors, Principal Investigators, DCP PIO personnel, DCP project officers, and others in the cancer research community.

CCS' Support Contract

CCS personnel support almost every aspect of DCP's research efforts. CCS personnel help DCP with protocol development, review, revisions, and amendments.

CCS support contract activities include:

- Protocol review and development
- Communication with the FDA
- Analysis of progress reports and close-out reports
- Review of protocol revisions and amendments
- Creation of case report forms
- Support of IRB approvals
- Production of quarterly reports
- Review of IND protocols

CCS' Monitoring Contract

CCS personnel perform many of the clinical trial monitoring tasks for DCP studies. Under this contract, CCS performs a function for the Division of Cancer Prevention that is similar to the role that the Clinical Trials Monitoring Branch performs for the Cancer Therapy Evaluation Program (CTEP).

CCS monitoring contract activities include:

- Site visits
- Initiation visits to sites
- Site audits
- Tracking protocol accruals
- QA of progress reports and close-out reports
- Tracking serious adverse event reports
- Analysis of case report forms
- Monitoring research contract milestones

The following activities span both the support and the monitoring contracts:

- Working with research study drug supplies
- Communicating with pharmaceutical companies
- Handling Office for Prevention of Research Risk (OPRR) assurances

CCS also performs the following activities that are not specifically covered by either contract:

- Write and/or edit scientific concepts
- Write and/or edit protocols
- Evaluate exceptions and deviations to protocols

CCS Interactions with the DCP Research Study Process

CCS performs activities throughout the life of a DCP study. CCS personnel perform review and communication functions in their support role. CCS personnel perform auditing, tracking and reporting functions in their monitoring role. CCS personnel may also assist in protocol development functions that are not clearly specified under their current contracts. CCS performs such development functions at the request of Medical Monitors or principal investigators.

Figure 1 follows CCS' functions throughout the life of a DCP research study. The figure displays CCS functions in yellow. The chart shows CCS monitoring functions in the top section and CCS support functions in the bottom section. The middle section contains CCS functions that are undefined regarding contract or that apply to both contracts. Non-CCS functions also appear in the middle section.

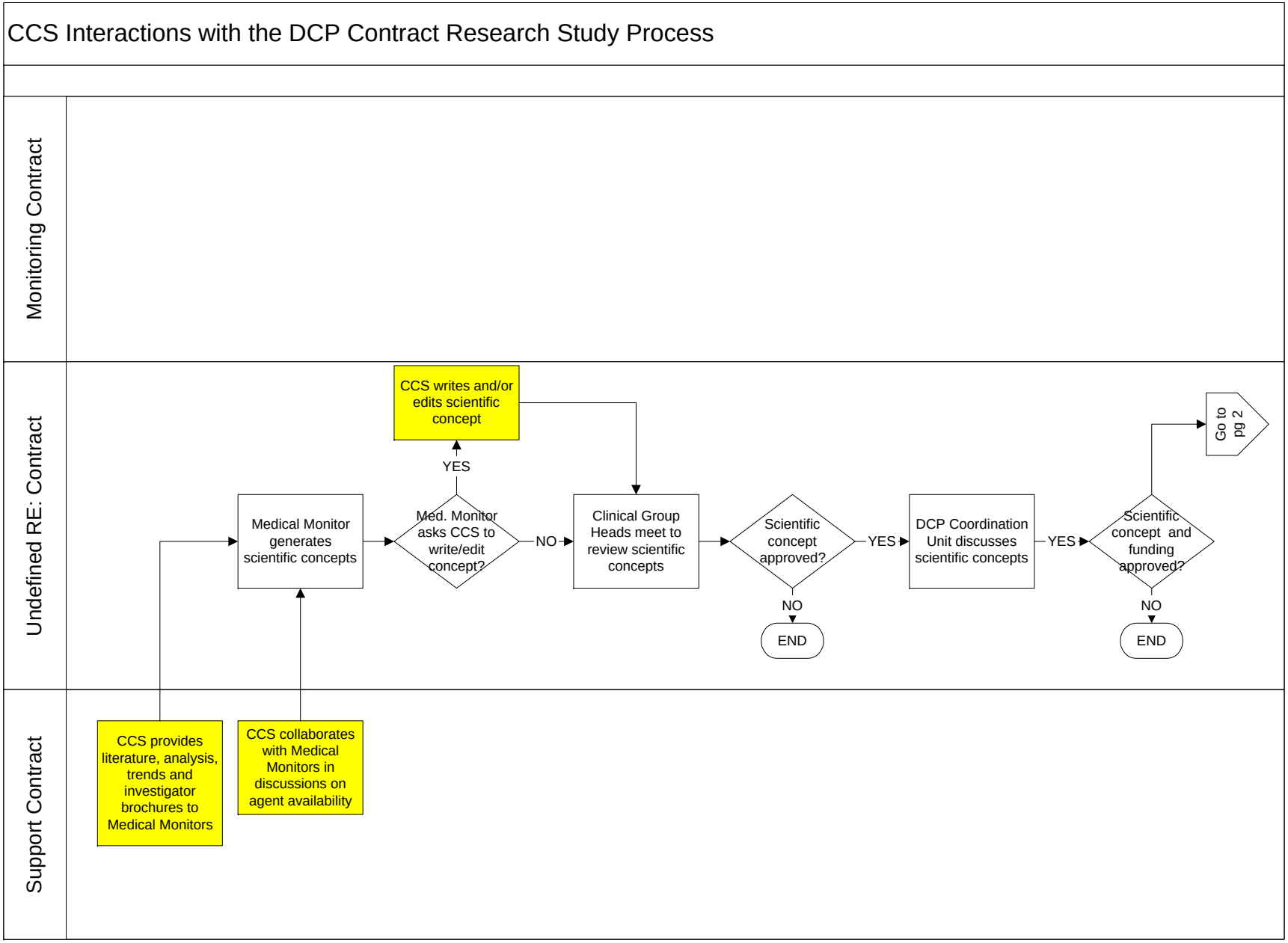


Figure 1: CCS Interactions with the DCP Research Study Process

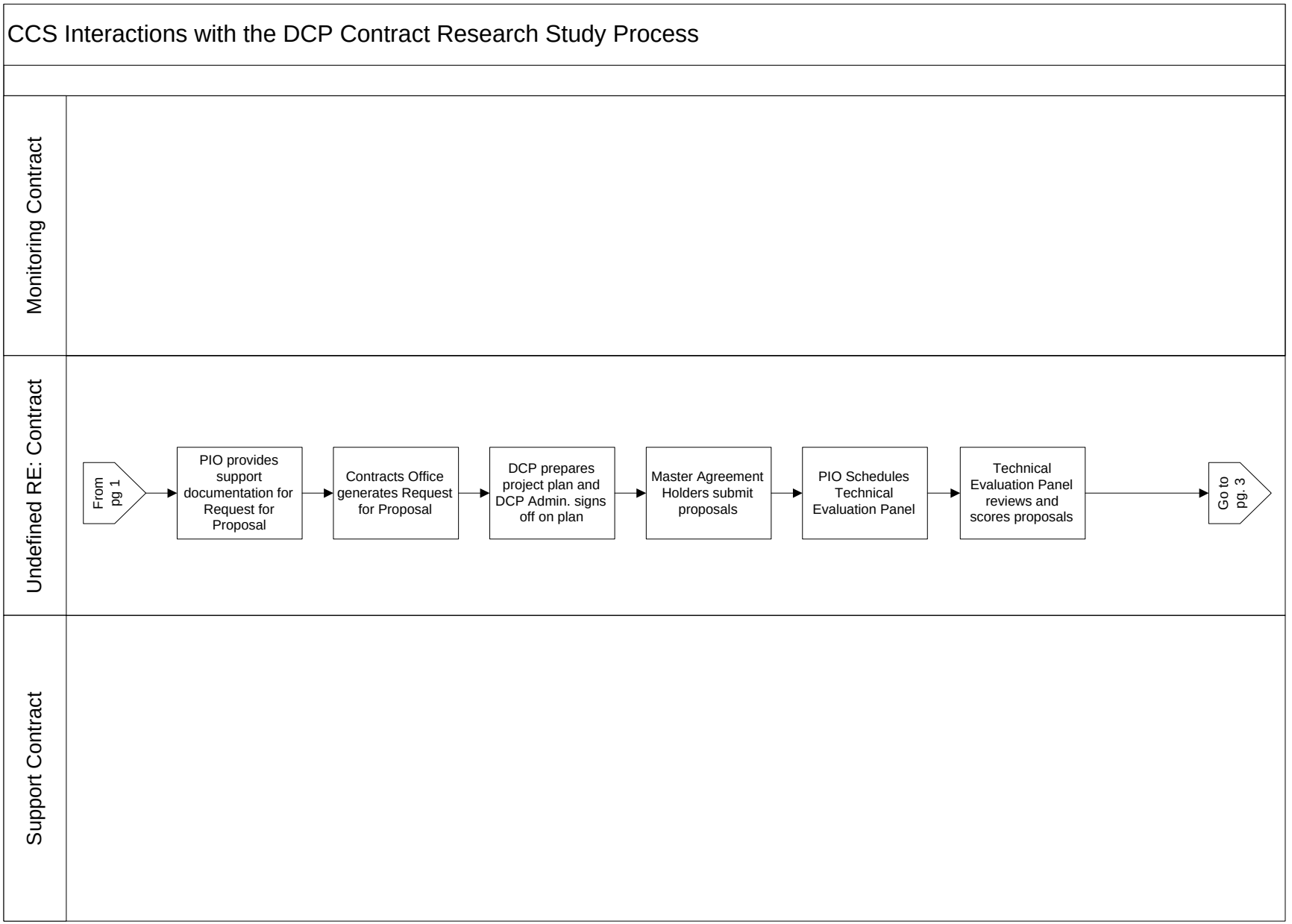
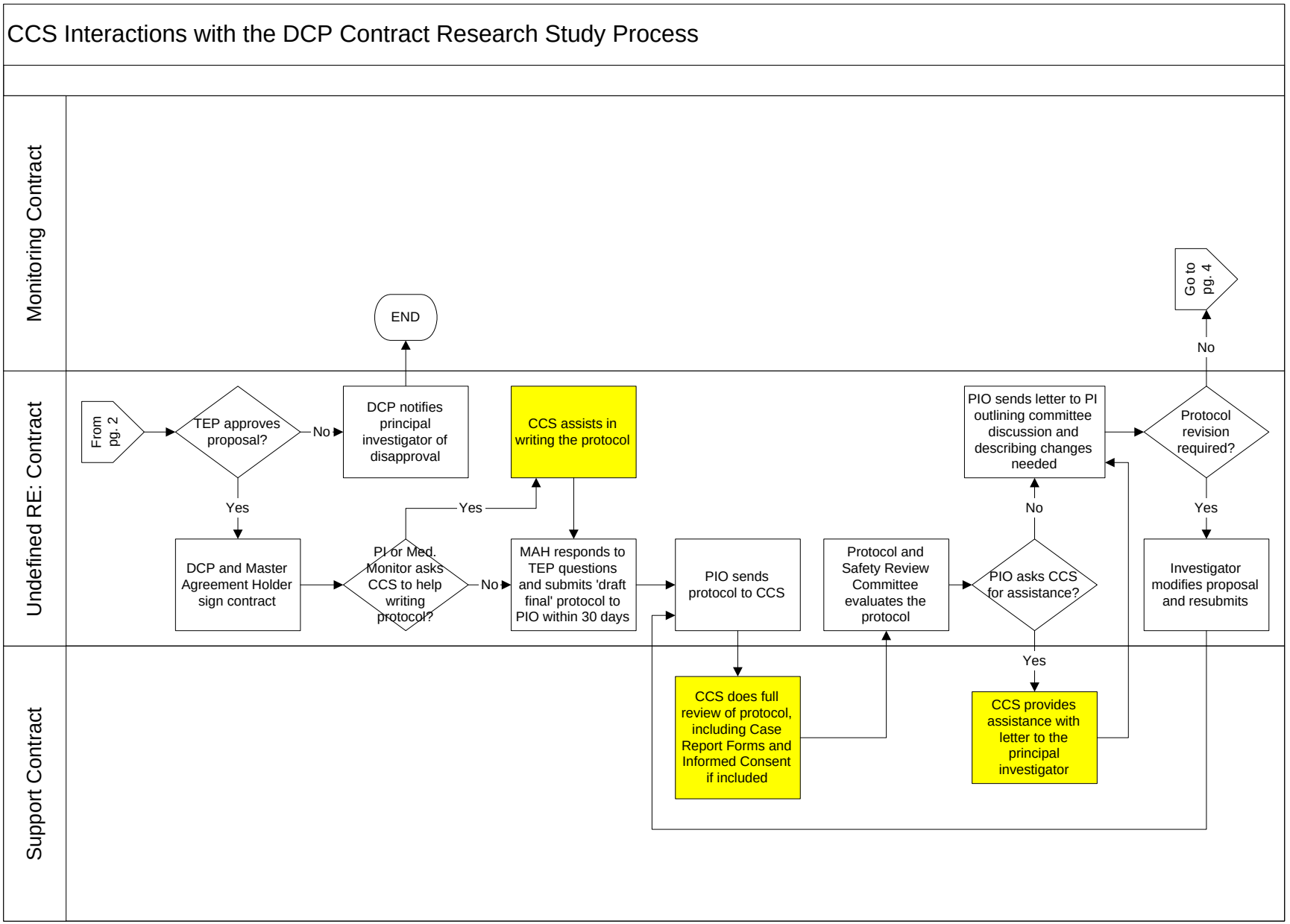


Figure 1: CCS Interactions with the DCP Research Study Process. (page 2)



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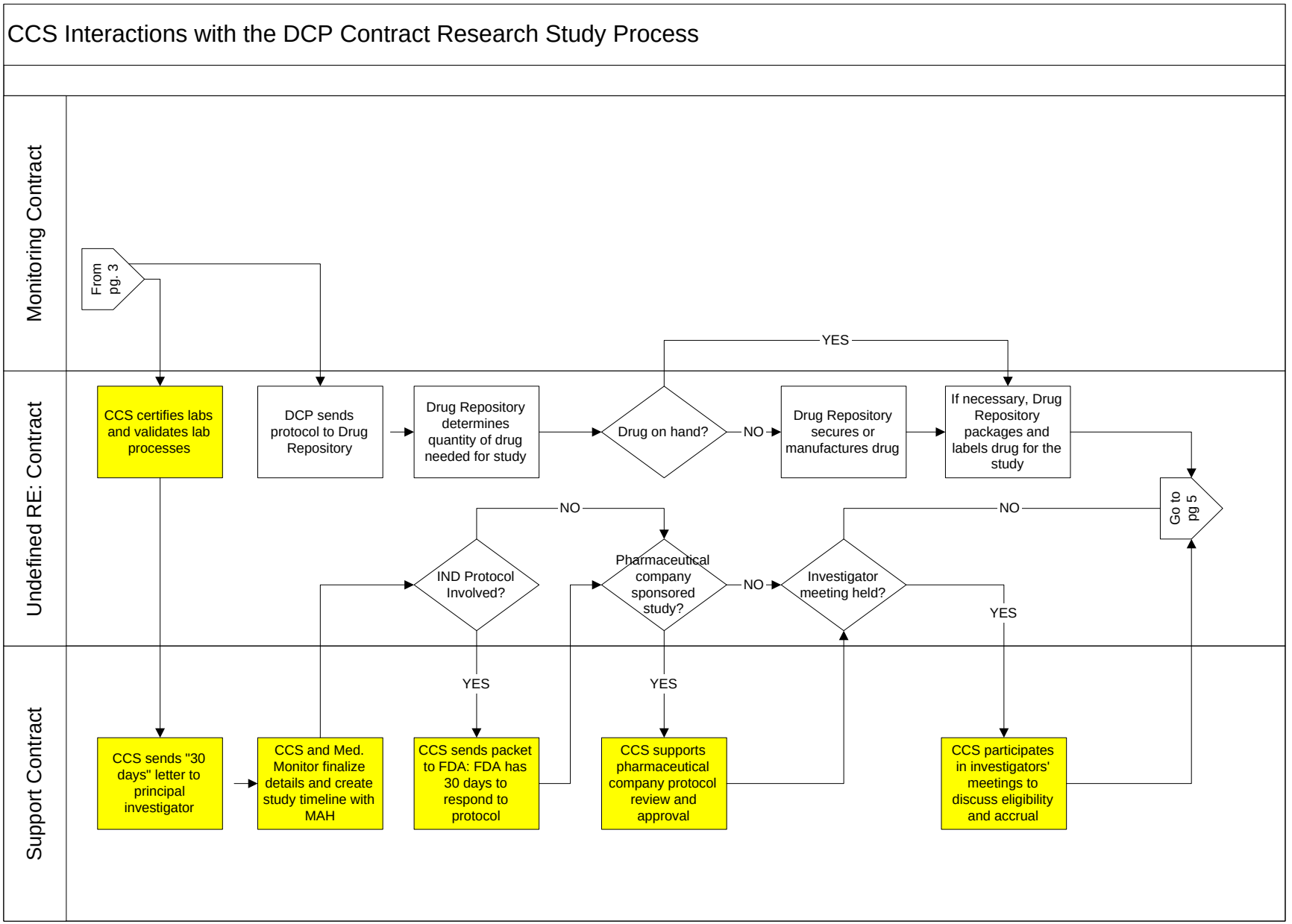

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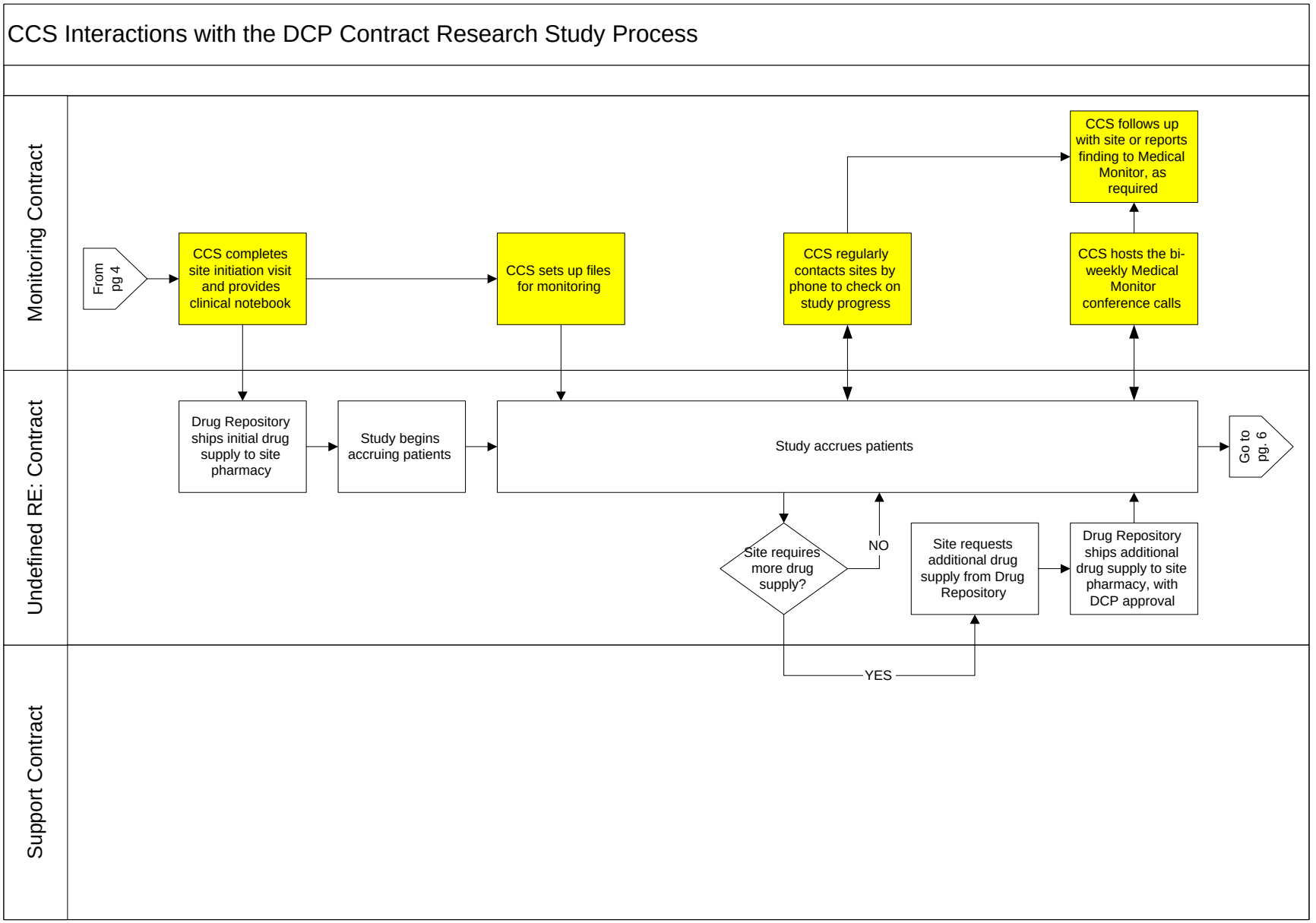

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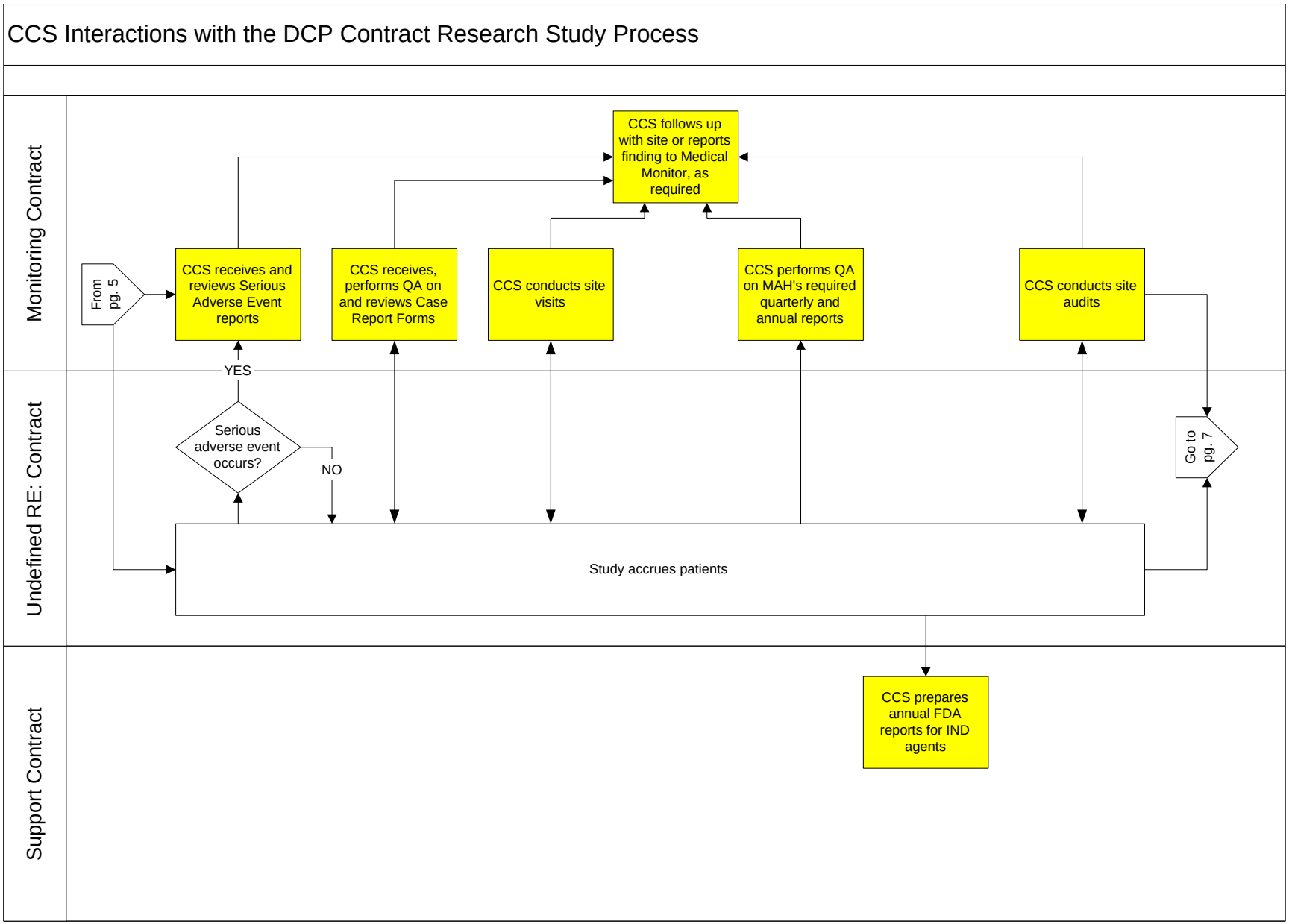

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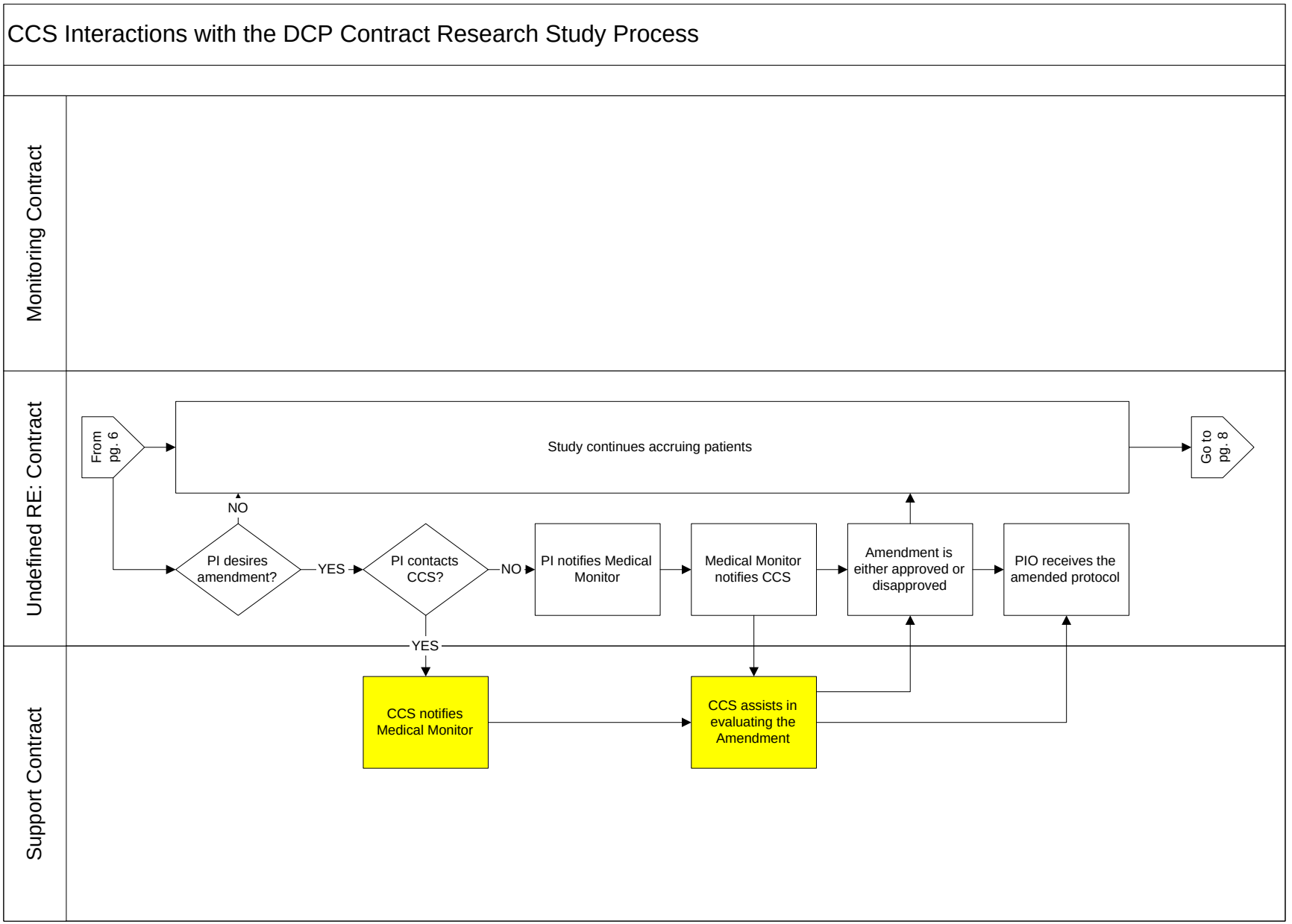

Figure 1: CCS Interactions with the DCP Research Study Process. (page 7)

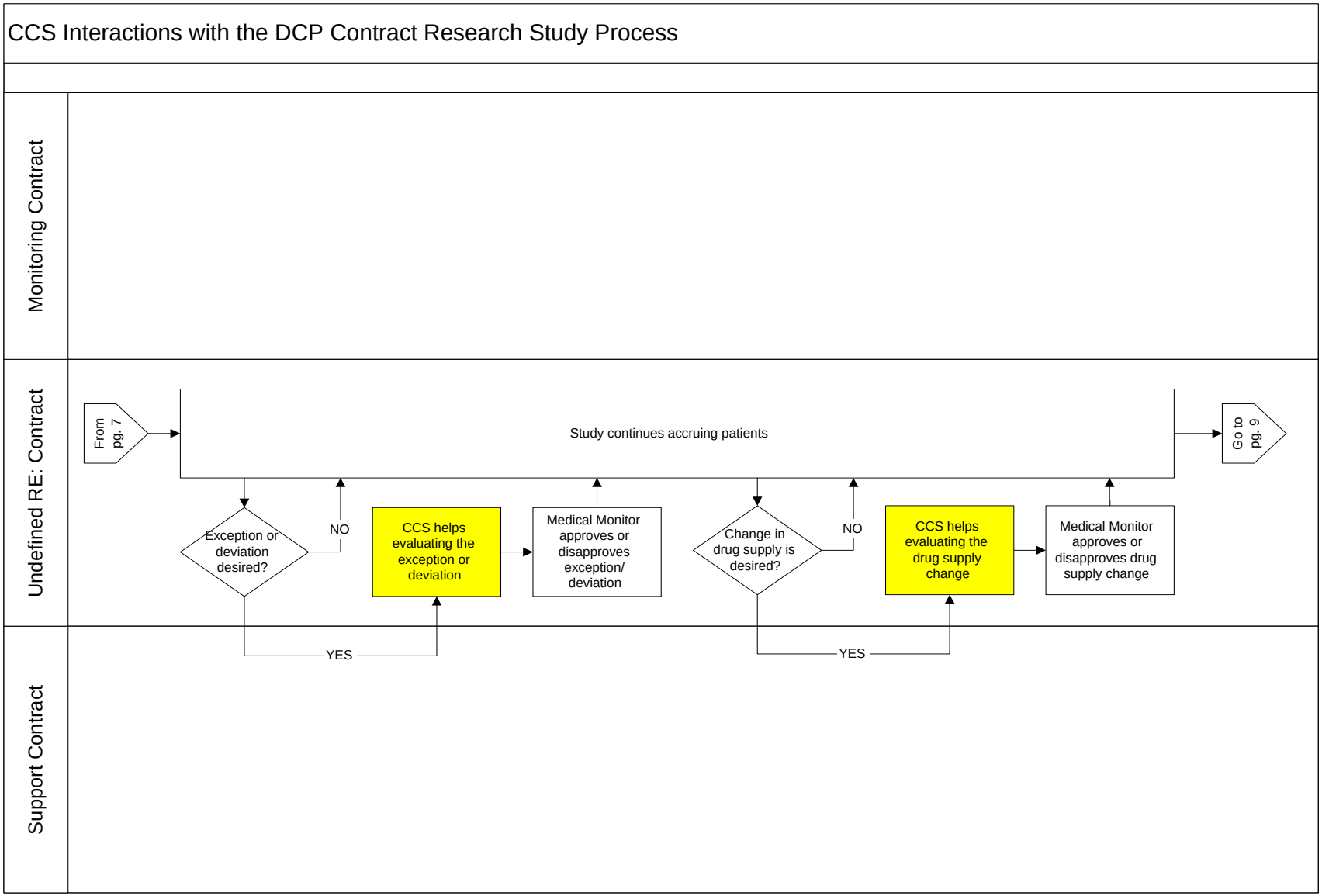

Figure 1: CCS Interactions with the DCP Research Study Process. (page 8)

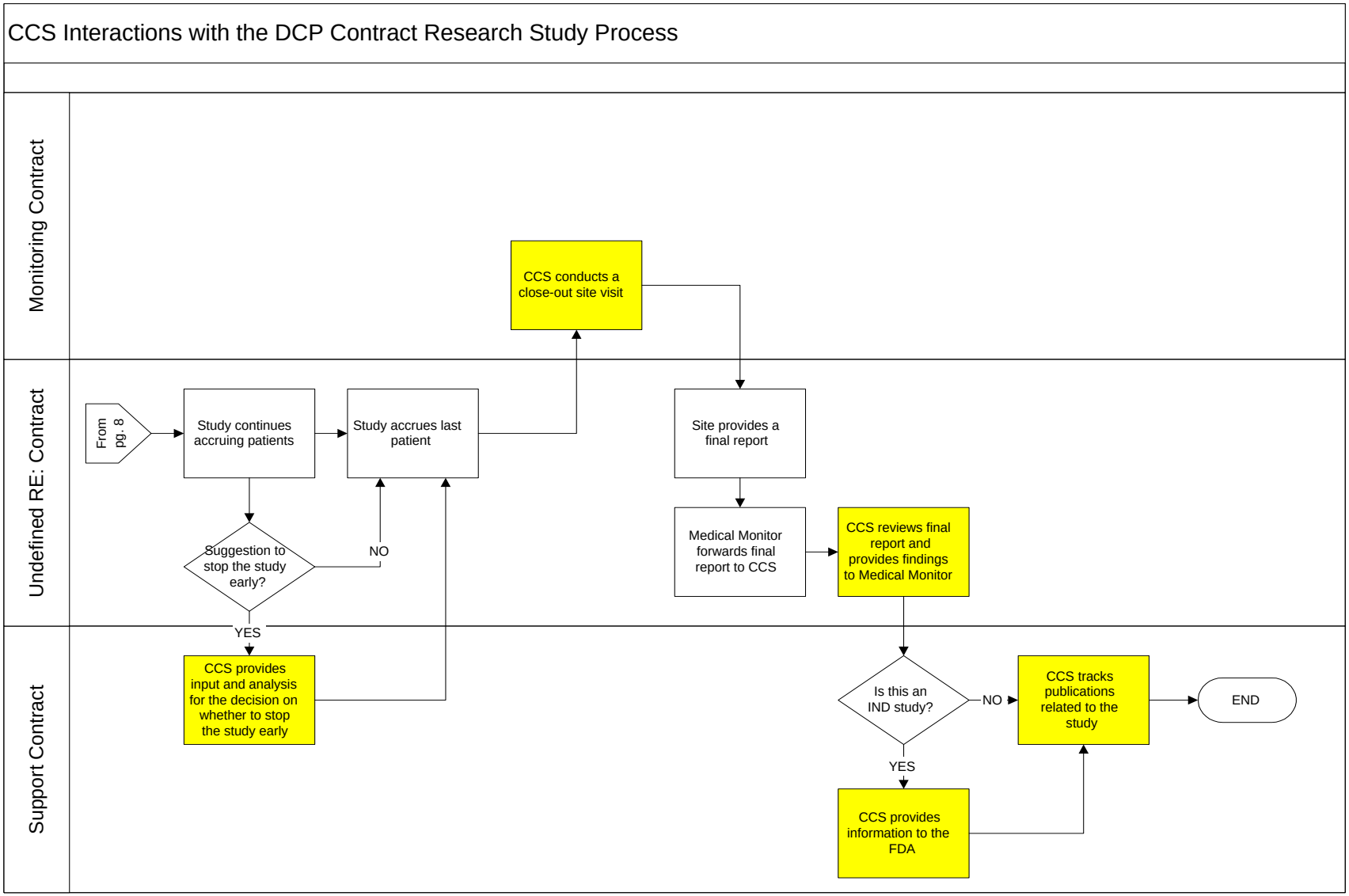

Figure 1: CCS Interactions with the DCP Research Study Process. (page 9)

Contacts Between Division of Cancer Prevention and CCS

CCS and DCP personnel communicate frequently regarding most aspects of DCP research studies. CCS communicates with a wide spectrum of DCP personnel by phone, email, and by Federal Express. Many communications between DCP and CCS involve activities from both the monitoring and the support contracts. An example is the every other Thursday teleconference where CCS personnel and Medical Monitors discuss various research study topics.

Figure 2 shows each contact event between CCS and DCP personnel in more detail. The chart displays the name and method of each contact inside a large arrow. The arrow's points indicate the direction(s) of that communication. The square at the left end of the arrow shows the DCP personnel involved in the communication. The square at the right end of the arrow shows the CCS personnel involved in the communication. The boxes below the arrow show the topics of communication, broken down into monitoring, support, and undetermined categories. Some topics overlap the monitoring and support categories.

Contacts Between Division of Cancer Prevention and CCS

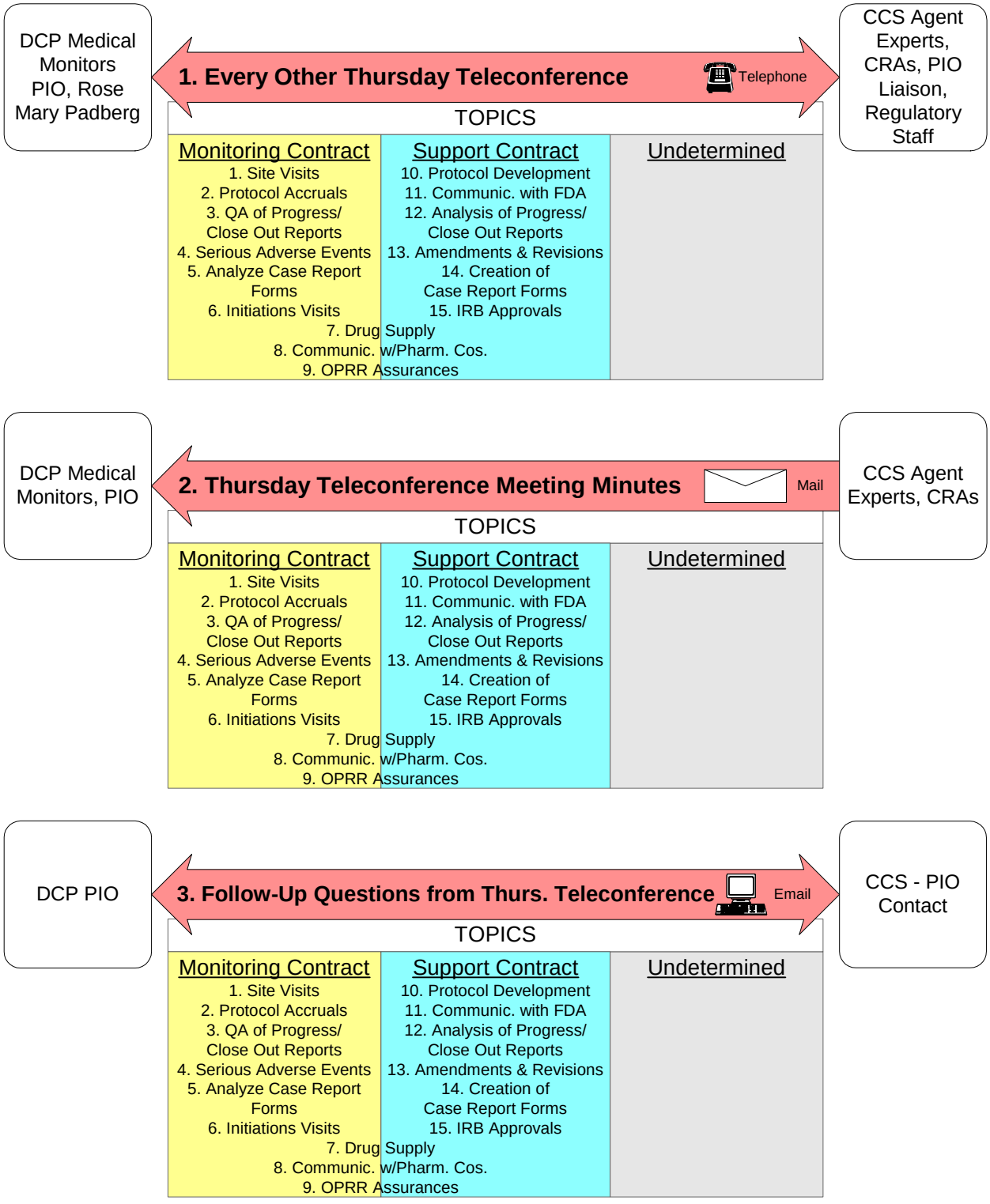

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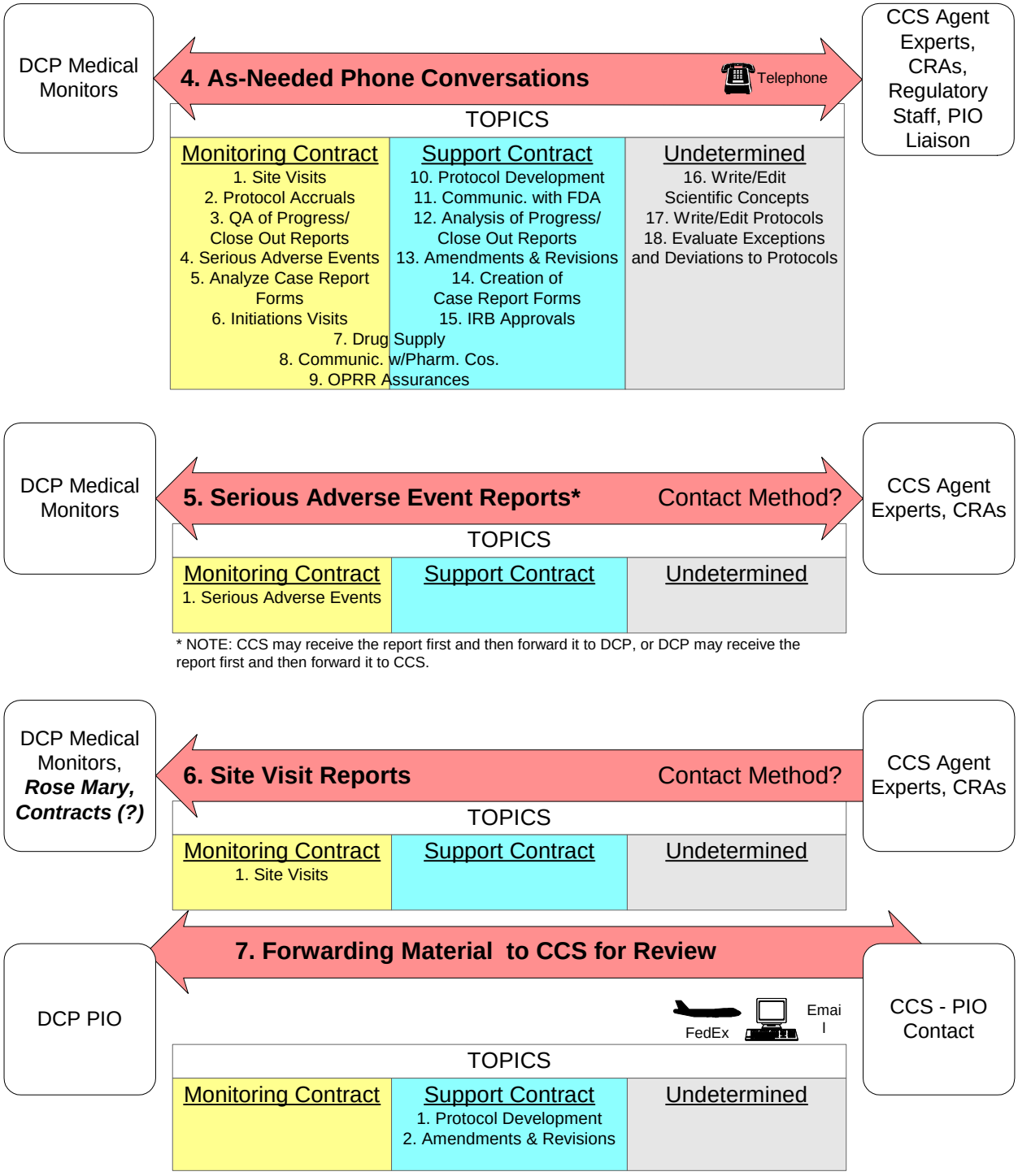
Figure 2: CCS Communication Organized by Contact Event

Contacts Between Division of Cancer Prevention and CCS



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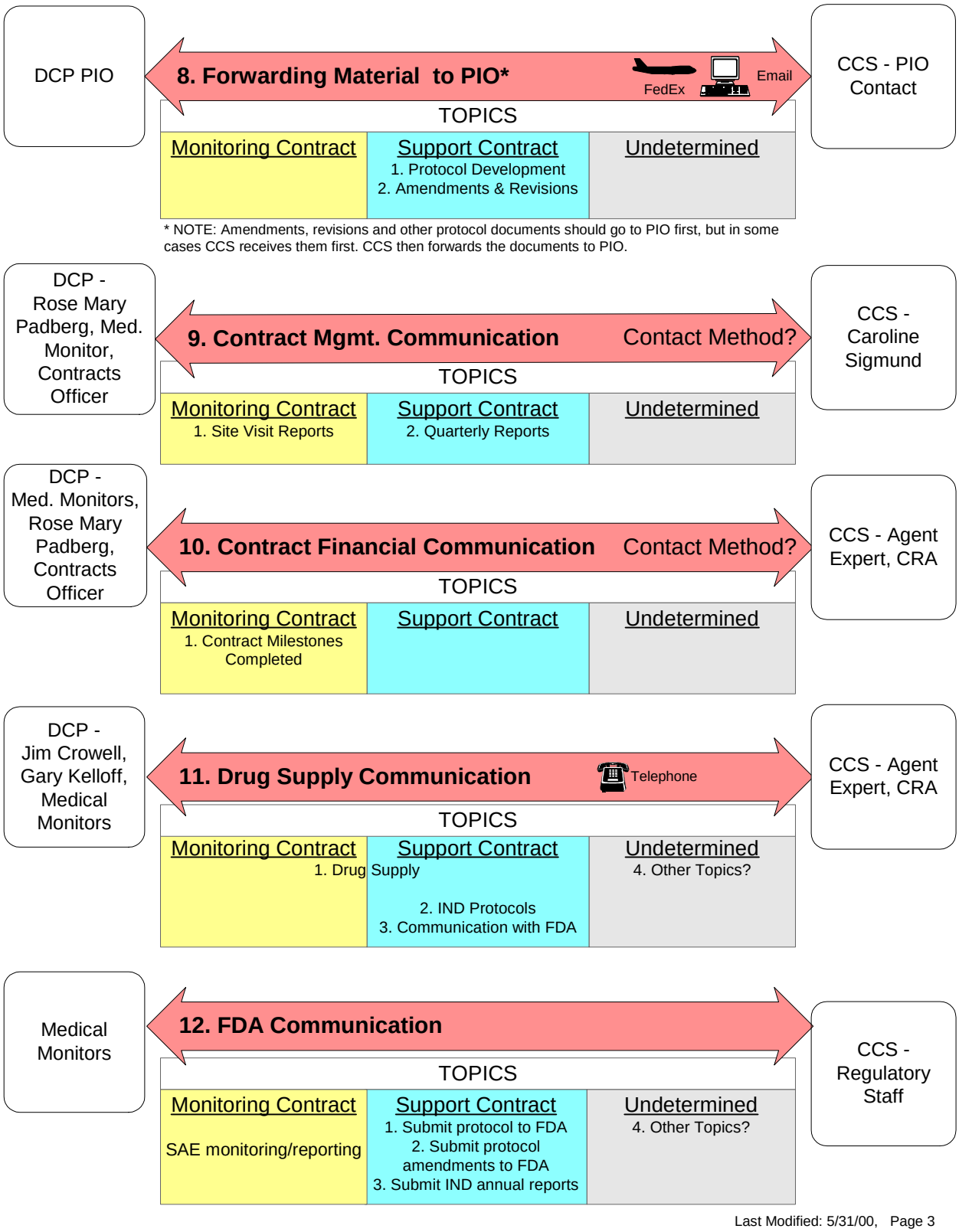

Figure 2: CCS Communication Organized by Contact Event. (page 3)

The communications between CCS and DCP fall into three categories:

- Teleconference Related
- Inquiries
- Document Related

The tables that follow further detail the contact events described in Figure 2. The number for each contact event in Tables 1, 2 and 3 corresponds to its number in Figure 2.

Table 1 presents the points of contact related to the teleconference categorized by event, topic of contact, who is contacted and the type of CCS contract.

Contact Event	**Topic of Contact**	**Who is Contacted / Method of Contact**	**CCS Contract Type**
1. Teleconference conducted every other Thursday	Topics of teleconference include topics related to both CCS monitoring and support contracts. Monitoring Contract: • Status of Protocols • Monitoring Visits • Protocol revisions and amendments • Adverse Events • Case Report Forms • Initiation Visits • IRB Approval Support Contract: • Communication with Pharmaceutical companies • Communication with FDA Topics relating to both contracts: • Progress Reports • Close-out Reports • Drug Supply • Office of Protection from Research Risk Assurances	Medical Monitors by phone	Monitoring and Support
2. Thursday teleconference minutes	All of the teleconference topics	DCP PIO by Email	Support and Monitoring (Minutes are a primary tool used for tracking contract studies)
3. PIO personnel has a question about the M.M. Minutes	All of the teleconference topics	Melissa at CCS by Email and Phone	Support and Monitoring

Table 1: CCS Communication: Teleconference Related

Table2 presents the points of contact related to inquiries. Each point categorized by event, topic of contact, who is contacted and the type of CCS contract.

Contact Event	**Topic of Contact**	**Who is Contacted / Method of Contact**	**CCS Contract Type**
4. Medical Monitors have a request	Medical Monitors may ask CCS to write/edit Scientific Concepts and Protocols. They may also request CCS to evaluate exceptions and deviations to Protocols. The Med. Monitor may discuss any of the topics on the Thursday teleconference	CCS is contacted by Medical Monitors as needed by Email and Phone	Monitoring and Support and undefined
10. Discussions about financial issues related to a Contract study	Study milestones are met	Medical Monitors and Master Agreement Holders like Georgetown by Email; Contracts Office; Rose Mary Padberg	More KA needed
11. Need to address drug supply issues	Anything related to Drug Supply	Jim Crowell may be contacted, or he may contact CCS. More KA needed on the method of contact. Gary Kelloff may also contact CCS or be contacted by them on these issues.	Support and Monitoring

Table 2: CCS Communication: Inquiries

Table3 presents the points of contact that are document related. Each point is categorized by event, topic of contact, who is contacted and the type of CCS contract.

Contact Event	**Topic of Contact**	**Who is Contacted / Method of Contact**	**CCS Contract Type**
5. Serious Adverse Event Reports	Dissemination of the Serious Adverse Event (SAE) reports	Medical Monitors. More KA needed on method of contact	Monitoring
6. Site Visit Reports	Forward site visit reports and discuss site visit results	Medical Monitors	Monitoring
7. Forwarding material to CCS for review	Forwarding of documents that PIO would like CCS to review	Melissa at CCS by Email and FedEx to PIO; Sometimes directly from the Medical Monitor to Clinical Research Associates, Agent Experts, or Regulatory staff at CCS	Monitoring
8. Forwarding material to DCP PIO	CCS has Protocol Documents that PIO needs	PIO Specialist by FedEx	Support
9. Contract management communication	Quarterly and site visit reports are sent to DCP and subsequent discussion	Rose Mary Padberg, Medical Monitors	Support and Monitoring

Table 3: CCS Communication: Document Related

Major Steps in a DCP Study

Protocol Information Office (PIO) personnel provided more information on their role in the Implementation and Amendment steps of a research study.

Review and Approval

PIO personnel reiterated that there is no clear endpoint separating the Review and Approval steps.

Implementation

Protocol Information Office personnel find their role during implementation to be less active than in other steps. The Implementation step begins after protocol approval notification is delivered and is completed once institutions begin accruing patients.

PIO personnel provided these details on their participation in the major step of Implementation:

- PIO staff does not always know when a study is initiated.
- PIO is not involved in Clinical Chemoprevention Oncology Program (CCOP) study implementation because the research bases perform most of the tasks.
- Investigational Review Board (IRB) approvals occur during the Implementation step. PIO is not involved in IRB approvals. PIO personnel receive any protocol revisions that result from IRB approvals.

Amendment

Research Bases send around sixty five percent of their CCOP amendments to them. The remaining CCOP amendments are sent to CTEP.

Entries for Domain Dictionary

Office for Prevention from Research Risk (OPRR) Assurance: Document that records the commitment of the research instruction to employ the basic ethical principles to protect the patient from unnecessary research risk. Depending on the situation, there are several kinds of assurance documents.

Case Report Form: A report written with a critical view of a patient's condition while participating in a clinical trial. The report incorporates all patient data as stipulated by the protocol.

Clinical Research Associate: Monitors investigator's adherence to study protocols and all FDA requirements relative to clinical research.

Medical Monitor: NCI Doctor responsible for monitoring the entire life of a Protocol. Originally a FDA term, 'Medical Monitor' is used by DCP PIO to describe different positions within the NCI who perform this function.

Site Visit Reports: A document used in clinical trial monitoring that records information gathered during a site visit to a cancer center or research institution.